



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,431	01/25/2002	Peter Paasch Mortensen	10127.200-US	9691
25908 7590 05/18/2007 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER DEJONG, ERIC S	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/057,431

Applicant(s)

MORTENSEN, PETER PAASCH

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-20, 28, 44, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-20, 44, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/05/2007 has been entered.

Claims 13, 21-27, 29-43, 45, and 46 are canceled. Claim 28 is withdrawn. Claims 1-12, 14-20, 44, 47, and 48 are currently under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 14-20, 44, 47, and 48 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Chandler et al. (US Patent No. 6,268,222).

The instant claims are drawn to a method of fluorescence analysis comprising illuminating a granular composition comprising a purified biologically active compound containing a fluorescent marker, detecting light emitted from the fluorescent marker, and predicting the amount of fluorescent marker in the granular composition. The prediction of the amount of fluorescent marker in the granular composition is accomplished by comparing the light emitted therefrom to data on light emitted from a known granular composition.

Chandler et al. sets forth the development and applications of novel fluorescent articles comprising a core particle region having on its surface a plurality of smaller polymeric particles stained with different fluorescent dyes (see Chandler et al., Abstract and throughout), which reads on a first and second granular composition comprising a core and a layer capable of fluorescence emission as recited in claim 1. Chandler et al. further discloses methods for detecting multiple subpopulations of analytes of interest employing a fluorescent, complementary binding moiety to each of said analytes, wherein each analyte and its complementary binding moiety comprise first and second members of a specific binding pair (see Chandler et al., col. 15, line 38 through col. 16, line 44). The disclosed method includes the steps of forming a mixture of the fluorescently labeled moieties of the binding pair, contacting the mixture and a solid support so that specific binding pairs are formed on solid supports, and relating the presence and concentrations of the analytes of interest in the sample by means of observing and quantifying a resultant fluorescence signal (see Chandler et al., col. 4, line 51 through col. 5, line 42 and Examples 1-11 at col. 16, line 55 through col. 24, line

Art Unit: 1631

53), which reads on detecting and obtaining data on emitted light from a first and second granular composition as recited in claim 1. Further, Examples 1 and 3 of Chandler et al. further sets forth an embodiment of the disclosed invention wherein different microparticle samples were stained with a predetermined amount of different fluorescent dyes, which reads on a first granular composition having known quality parameters as recited in claim 1. The different microparticle samples were further mixed together at different ratios to form a new series of samples, which reads on a second granular composition as recited in claim 1 and. Treating this ratio as an unknown, Chandler et al. sets forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles, which reads on predicting the amount of fluorescent marker of the second granular composition as recited in claim 1, a prediction including comparing light from a second composition to that of the first known composition as recited in claim 10, and a prediction made in real time as recited in claim 11. The fluorescence intensity measured from each of the new series of samples allowed for the determination and back calculation of the particular ratio of different microparticles. Therefore, Chandler et al. further anticipates the method of claim 44 in the above example by demonstration of a calibration model from granular compositions of known quality that, by comparative means, are used to evaluate the quality of samples of unknown quality.

The disclosed fluorescent particles range from 0.1 to 1,000 μM in diameter (see Chandler et al., col. 3, lines 9-20), which reads on a first and second granular composition having an average size between 20-2000 μM as recited in claim 20. Chandler et al. further discloses that the composition of the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents and to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64) that allow for interaction with and, subsequently, the detection of antigens, proteins, enzymes, and other biological molecules (see Chandler et al., col. 3, lines 56-62 and col. 4, lines 45-50), which reads on granular compositions comprising a purified enzyme as recited in claim 1, a homogenous substantially continuous layer of purified enzyme disposed on a core as recited in claims 19 and 47, an enzyme bio-catalyst or therapeutic agent as recited in claim 12, and granular compositions that further comprise auxiliary granulation agents as recited in claims 15-18. Further, Example 11 of Chandler et al. teaches specific embodiments of enzymes for use with the disclosed micro/nanoparticles that are hydrolases and oxidoreductases, which reads on the enzyme is a hydrolase or oxidoreductase as recited in claim 14. The fluorescent particles are further disclosed as being capable of emitting a single fluorescence emission or multiple fluorescence emissions with emission spectra ranging from 450 nm to 1000 nm (see Chandler et al., col. 4, lines 15-30), which reads on the emitted light of 1-10 discrete monochromatic wavelengths as recited in claim 5 and 6. Further, fluorophores that emit light at and above 450 nm are inherently excited to fluoresce by sources of ultraviolet light in the range of 10-350 nm as recited in claims 2-4. The

Art Unit: 1631

detection means disclosed for observing and measuring fluorescence emissions includes, digital cameras (CCD) as well as other means for converting observed light into digital signals and two-dimensional images (see Chandler et al., col. 4, line 59 through col. 5, line 4), which reads on the at least one detector and at least two detectors as set forth in claims 7-9 and converting emitted light into an electronic signal as recited in claims 44 and 48.

Response to Arguments

Applicant's arguments filed 03/05/2007 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 102(e)(2) as being anticipated by Chandler et al.; applicants argue that Chandler et al. does not describe a granular composition having a core and a layer of purified enzyme disposed thereon. Applicants further argue that Chandler et al. describes a fluorescent article including a core or carrier particle having on its surface a plurality of smaller polymeric particles or nanoparticles, which are stained with different dyes.

In response, it is reiterated from the above rejection that Chandler et al. sets novel fluorescent articles comprising a core particle region having on its surface a plurality of smaller polymeric particles stained with different fluorescent dyes (see Chandler et al., Abstract and throughout), which reads on a first and second granular composition comprising a core and a layer capable of fluorescence emission as recited

Art Unit: 1631

in claim 1. Further, Chandler et al. discloses that the composition of the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents and to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64) which reads on granular compositions comprising a purified enzyme as recited in claim 1. Further, Example 5 of Chandler et al. sets forth an exemplary embodiments wherein a purified enzyme was covalently attached to the surface disclosed nanoparticles. Therefore applicants argument is not found persuasive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631

A handwritten signature in black ink, appearing to read "Eric DeJong", with a stylized flourish at the end.